

1. Specification

The Office Action objects to the amendment as introducing new matter. The Office Action states:

35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to paragraphs 15 and 26 of the specification (those that specifically alter numerical ranges) are not supported by the specification as originally filed.

Applicant respectfully traverses the objection to the amendments to the specification because each of the amended ratio ranges is clearly supported by the disclosed preferred ranges. For example, the IL-10 to IL-2 ratio in paragraph 15 of the specification has been amended to recite a ratio range of "2.82 to 3.22" from "2.87 to 3.22". Support for the lower bound of 2.82 is disclosed in the preferred range of 3.0 +/-0.18. The lower limit of 2.82 is supported by the fact that the preferred range 3.0 +/-0.18 provides that the lower limit of the preferred range is:

$$3.0 - 0.18 = 2.82$$

Therefore, support is provided for the lower range of 2.82. If the amendment is not entered, the currently pending lower bound of 2.87 is outside the range of the preferred range of 3.0 +/-0.18.

The IL-16 to IL-2 ratio in paragraph 15 of the specification

has also been amended to recite a ratio range of "1.16 - 2.84" from "1.24 - 2.84". Support for the lower bound of 1.16 is disclosed in the preferred range of 1.84 +/-0.68. The lower limit of 1.16 is supported by the fact that the preferred range 1.84 +/-0.68 provides that the lower limit of the preferred range is:

$$1.84 - 0.68 = 1.16$$

Therefore, support is provided for the lower range of 1.16. Again, if the amendment is not entered, the currently pending lower bound of 1.24 is outside the range of the preferred range of 1.84 +/-0.68.

The TNF- β to IL-2 ratio in paragraph 15 of the specification has been amended to recite a ratio range of "1.17 - 2.43" from "1.18 - 2.43". Support for the lower bound of 1.17 is disclosed in the preferred range of 1.8 +/-0.63. The lower limit of 1.17 is supported by the fact that the preferred range 1.8 +/-0.63 provides that the lower limit of the preferred range is:

$$1.8 - 0.63 = 1.17$$

Therefore, support is provided for the lower range of 1.17. Again, if the amendment is not entered, the currently pending lower bound of 1.18 is outside the range of the preferred range of 1.8 +/-0.63.

The MIP-1 α to IL-2 ratio in paragraph 15 of the specification has been amended to recite a ratio range of "**15.7** - 37.16" from "16.78 - 37.16". Support for the lower bound of **15.7** is disclosed

in the preferred range of 22.7 +/-7.0. The lower limit of **15.7** is supported by the fact that the preferred range 22.7 +/-7.0 provides that the lower limit of the preferred range is:

$$22.7 - 7.0 = 15.7$$

Therefore, support is provided for the lower range of **15.7**. Again, if the amendment is not entered, the currently pending lower bound of 16.78 is outside the range of the preferred range of 22.7 +/-7.0.

The MIP-1 β to IL-2 ratio in paragraph 15 of the specification has been amended to recite a ratio range of "19.2 -26.4" to "17.1 - 28.5". Support for the range is disclosed in the preferred range of 22.8 +/-5.7. The lower limit of 19.2 is supported by the fact that the preferred range 22.8 +/-5.7 provides that the lower limit of the preferred range is:

$$22.8 - 5.7 = 17.1$$

The upper limit is

$$22.8 + 5.7 = 28.5$$

Therefore, support is provided for the lower range of 17.1 - 28.5.

The EGF to IL-2 ratio in paragraph 15 of the specification has been amended to recite a ratio range of "0.267 - 0.283" from "0.27 - 0.28". Support for the range is disclosed in the preferred range of 0.275 +/-0.008. The lower limit of 0.267 is supported by the fact that the preferred range 0.275 +/-0.008 provides that the

lower limit of the preferred range is:

$$0.275 - 0.008 = 0.267$$

The upper limit is

$$0.275 + 0.008 = 0.283$$

Therefore, support is provided for the lower range of 0.267 - 0.283.

The PGE₂ to IL-2 ratio in paragraph 15 of the specification has been amended to recite a ratio range of "3.63 - 5.42" from "3.68 - 5.42". Support for the lower bound of **3.63** is disclosed in the preferred range of 4.5 +/-0.87. The lower limit of **3.63** is supported by the fact that the preferred range 4.5 +/-0.87 provides that the lower limit of the preferred range is:

$$4.5 - 0.87 = 3.63$$

Therefore, support is provided for the lower range of **3.63**.

The TxB₂ to IL-2 ratio in paragraph 15 of the specification has been amended to recite a ratio range of "23.47 - 25.13" from "23.5 - 25.1". Support for the range is disclosed in the preferred range of 24.3 +/-0.83. The lower limit of 23.47 is supported by the fact that the preferred range 24.3 +/-0.83 provides that the lower limit of the preferred range is:

$$24.3 - 0.83 = 23.47$$

The upper limit is

$$24.3 + 0.83 = 25.13$$